

ORIGINAL ARTICLE

Medical Applications and Outcomes of Bitangential Scleral Lenses

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ABSTRACT

Purpose. To evaluate the clinical results of a new scleral lens design with a bitangential (nonrotationally symmetrical) periphery.

Methods. All the necessary data were obtained during the 1-year study period. The bitangential scleral lenses were fitted and monitored according to a standardized fitting methodology. They were cut by precise submicron lathing from high-oxygen-permeable materials (including 10 scleral lenses from Menicon Z material). Subjective performance, visual acuity, and scleral lens-fitting characteristics were recorded after a median of 9.4 weeks (range, 3 weeks to 1 year).

Results. Diagnoses in the 213 eyes (in 144 patients) were keratoconus (n = 121 eyes; 56.8%), ocular surface diseases (n = 31 eyes; 14.6%), penetrating keratoplasty (n = 29 eyes; 13.6%), and other forms of irregular astigmatism (n = 28 eyes; 13.1%). Many patients (164 lenses; 77.0%) gave high ratings for comfort. The most common diameter was 20.0 mm (162 lenses; 76.1%) (range, 18.5 to 21.5 mm). Median decimal best-corrected visual acuity with the bitangential scleral lenses was 0.8 (equivalent to Snellen 20/25) (range, 0 to 1.5). Most bitangential scleral lenses showed good fitting characteristics: optimal values were seen for lens movement (208 lenses; 97.7%) and lens position (208 lenses; 97.7%). Median central corneal clearance was 0.2 mm; clearances differed in the four peripheral directions. The median stabilization axis was 140 degrees (range, 0 to 180 degrees) in the right eyes and 60 degrees (range, 0 to 180 degrees) in the left eyes.

Conclusions. The bitangential scleral lens-fitting and performance characteristics were clear and effective for the health professional and the patient. The high-oxygen-permeable material Menicon Z may, in theory, be of benefit to corneas with a high oxygen demand.

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Key Words. new scleral lens design, bitangential, bitoric, keratoconus, penetrating keratoplasty, irregular astigmatism, ocular surface disease

Scleral contact lenses have become increasingly popular among eye care practitioners who fit patients for medical indications. A scleral lens has various unique advantages, such as the retention of a precorneal fluid reservoir that affords simultaneous corneal hydration and optical correction of the irregular corneal surface. The rigidity of the material provides optical correction and mechanical protection. As a result, scleral lenses are effective in the

management of irregular, fragile, and diseased corneas, as well as dry eyes. Keratoconus and other forms of irregular astigmatism comprise the major group of indications.

The clinical application of scleral lenses began with the work of Fick¹ and Müller² in the 1880s. Since then, diagnostic trial lens fitting, high-oxygen-permeable materials, and technological innovations in design and manufacturing have extended the use of scleral lenses.

Ezekiel³ evaluated the use of gas-permeable scleral lenses in 1983 and reported greater acceptability and comfort with the oxygen-permeable scleral lenses than the polymethylmethacrylate versions. Further development of materials with high gas permeability has led to better performance of scleral lenses.^{4–12} In 2006, Visser et al.^{13–15} reported that the availability of toric scleral lenses enabled more precise scleral lens fitting and resulted in greater patient satisfaction. More recently, several reports on the use of

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rotationally symmetrical scleral lenses as well as toric and quadrant-specific scleral lens designs have illustrated the renewed interest in these devices by health professionals and industry.^{16–20}

Van der Worp et al. reported findings that have important clinical consequences on the fitting and design of scleral lenses.²¹ They found that toricity was more pronounced in the scleral than in the limbal area, irrespective of the toricity of the cornea. This suggests that nonrotationally symmetrical scleral lenses might be preferable to rotationally symmetrical scleral lenses. They also showed that, in most cases, the shapes of the limbus and anterior sclera were tangential rather than curved. On the basis of these findings, they concluded that, when fitting scleral lenses, the use of tangential angles, rather than curves, may be appropriate in the majority of cases.^{21,22}

This body of information formed the starting point to design a new scleral lens with a bitangential (nonrotationally symmetrical) periphery. The tangential periphery aims to enable gentle positioning on the scleral surface, increased fitting tolerance, and optimal centration. We found one earlier reference to tangential fitting in the Feincone Contact Lens Series described by Feinbloom²³ in the 1940s. The object of tangential fitting was to reduce the adhesive pressure on the eye, to achieve greater tolerance, and to prolong the daily duration of use.^{23,24}

The adjustable flat or steep meridian of this bitangential scleral lens design aims to distribute the lens pressure more equally over the sclera and improve the scleral lens fit, with less risk of air bubble formation behind the lens, or local blanching of the conjunctival scleral vessels. The latter disadvantages occur with rotationally symmetrical scleral lenses fitted to toric or irregular anterior scleral surfaces because the edges are locally too flat or too steep.

This study evaluated the clinical findings with the bitangential scleral lens design.

METHODS

All the scleral lenses applied in this study were fitted diagnostically with trial lenses, according to our standardized fitting methodology. During this fitting procedure, a trial lens was selected by evaluating the corneal and scleral profile macroscopically and with slit lamp examination. The fitting set consisted of 35 trial lenses with a diameter of 20.0 mm. If a trial lens did not fit correctly, it was replaced by a trial lens with the correct fit, which was then used to determine the exact size of the five parameters: sagittal depth, central radius (BCR), tangent angle of the flattest meridian of the scleral part, tangent angle of the steepest meridian of the scleral part, and total lens diameter. Fitting was based on resting the lens on the external sclera and vaulting over the cornea and limbus. An ideal lens was characterized by well-balanced haptic bearing, gentle movement of the lens with the push-up test, and adequate corneal and limbal clearance. The desired apical clearance was about 0.2 mm but varied according to the diagnosis or circumstances (Fig. 1). Insufficient clearance (corneal touch) should be avoided because it would cause mechanical pressure on the cornea, which might disturb the corneal physiology and decrease comfort and tolerance. However, excessive clearance (>0.5 mm) would make it more difficult to insert the lens without air bubbles. In eyes that tend to accumulate debris behind the lens, a smaller sagittal depth needs to be chosen because an increased

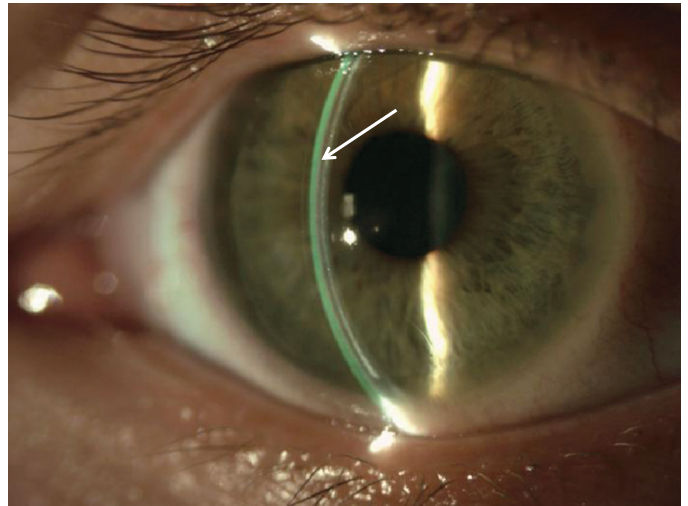


FIGURE 1.

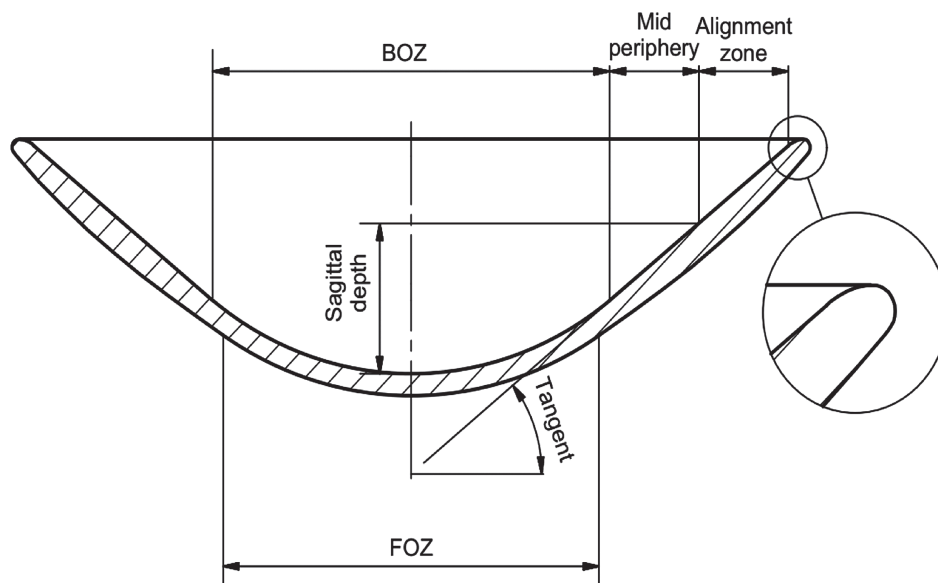
Apical clearance. A color version of this figure is available online at www.optvissci.com.

volume of cloudy clearance will directly affect the patient's visual acuity (VA). In contrast, a larger sagittal depth may be necessary in eyes that are prone to progressive ectasia. Furthermore, the cornea may have so many irregularities that the sagitta has to differ locally, for example, in tilted transplants.

Data were gathered during the regular check-up visits between April 2011 and April 2012. One data set per patient was used for our analyses. We selected the data from the check-up visit in which the scleral lens had been worn for the longest duration (range, 3 weeks to 12 months). Lenses had been fitted or refitted at the scleral lens clinics at Visser Contact Lens Practice. All the patients who had been wearing one or two bitangential scleral lenses for at least 3 weeks and who gave informed consent (or their legal representatives in the case of minors) took part in the study. They had been referred to the clinic by their ophthalmologist on account of keratoconus, penetrating keratoplasty, other forms of irregular astigmatism, ocular surface disease (OSD), or other indications. The scleral lenses were being worn on a daily basis. Patients were instructed to clean, wet, and disinfect their scleral lenses using standard rigid gas-permeable lens solution systems. They were also advised to fill the lenses with unpreserved saline or the more viscous alternative, unpreserved sodium carboxymethyl cellulose 1.0% (Cellumed; Allergan Pharmaceuticals, Westport, Ireland). The latter was especially recommended in patients who consistently had air bubbles trapped behind the lens on insertion.

We recorded sex, date of birth, and diagnosis. Patients were asked to rate the comfort of their lenses on a five-point scale, which ranged from 1 (very poor) to 5 (excellent). The best-corrected VA (BCVA) (in decimal form) was determined, as well as the over-refraction. To convert Snellen VA into decimal VA, the numerator must be divided by the denominator. Thus, a result of 20/25 is equivalent to the decimal score of 0.8.

Lens-fitting characteristics were assessed during the routine slit lamp examination. Corneal and limbal clearances were estimated in millimeters in five positions: central, superior, inferior, nasal, and temporal. This was done using visual approximation based on the thickness of the cornea and the scleral lens; thickness of a

**FIGURE 2.**

Bitangential scleral lens design: BOZ, back optic zone; FOZ, front optic zone.

trial lens = 0.4 mm. Lens movement was determined with the push-up test and graded according to our own system, which ranged from -2 (no lens movement) to +2 (excessive lens movement).¹⁴ The position of the lens could be marked as central, or grade 1 (acceptable), or grade 2 (undesirable) decentration in a nasal, temporal, superior, or inferior direction. The stabilization axes were measured and recorded in degrees.

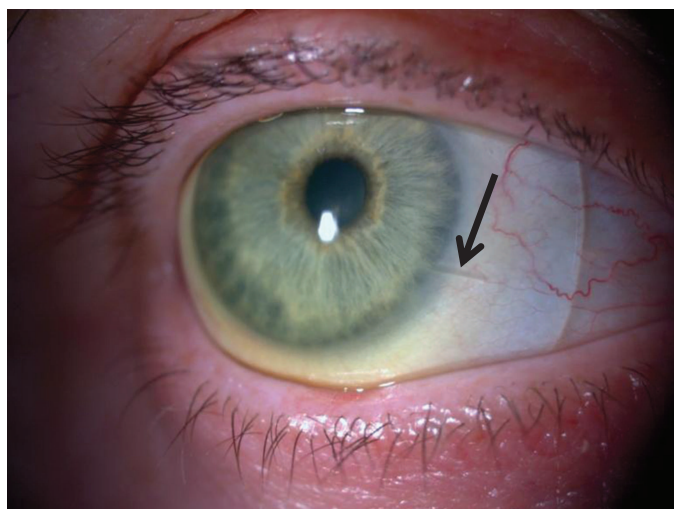
The new scleral lens design was realized in cooperation with NKL Contactlenzen (Emmen, the Netherlands) (Fig. 2). It is defined by a front optical zone of 9.5 mm, a spherical back optical zone of 10 mm, and a midperipheral zone that vaulted the limbal area. The midperipheral zone has a width of 2 to 3 mm, depending on the overall lens diameter. This zone is smoothly connected to the optical zone and the linear alignment zone. The linear alignment zone is connected to the edge by an edge curve, which supplies extra edge clearance. The linear alignment zone is described by two meridians with different tangential angles to enable gentle application to the sclera. A large tangential angle implies a steeper haptic, whereas a smaller angle leads to a flatter scleral fit. In this way, two adjustable meridians are achieved: a flat and a steep meridian. These two different meridians of the linear alignment zone are 90 degrees apart and make the back surface nonrotationally symmetrical, a so-called toric surface. The flattest meridian was marked with two engravings (Fig. 3). The stabilization axis could be measured by projecting a narrow beam from the slit lamp parallel to the engravings on the scleral lenses. The axis could then be read from the protractor.

Parameters could be chosen independently at the request of the fitter. Each lens was engraved with a code that matched the parameters of the lens. Power range, including cylinders, was unlimited. The bitangential scleral lenses were cut by precise submicron lathing from high-oxygen-permeable materials. The materials used in this study were Boston Equalens II (Oprifocon A, Dk 85), Boston XO (Hexafocon A, Dk 100), Boston XO2 (Hexafocon B, Dk 161), and Menicon Z (Tisilfocon A, Dk 189). Dk of the first

two materials was listed following the Polarographic ISO/Fatt method, whereas the latter two materials were listed following the non-edge-corrected ISO/Fatt method. Boston materials were manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, whereas the Menicon Z material was produced by Menicon Co. Ltd., Nagoya, Japan. At the time of this study, only a very limited amount of the Menicon Z material was available.

RESULTS

Evaluation was performed after a median of 9.4 weeks of wearing the new design and ranged from 3 weeks to 1 year.

**FIGURE 3.**

Engravings on the bitangential scleral lens. A color version of this figure is available online at www.optvissci.com.

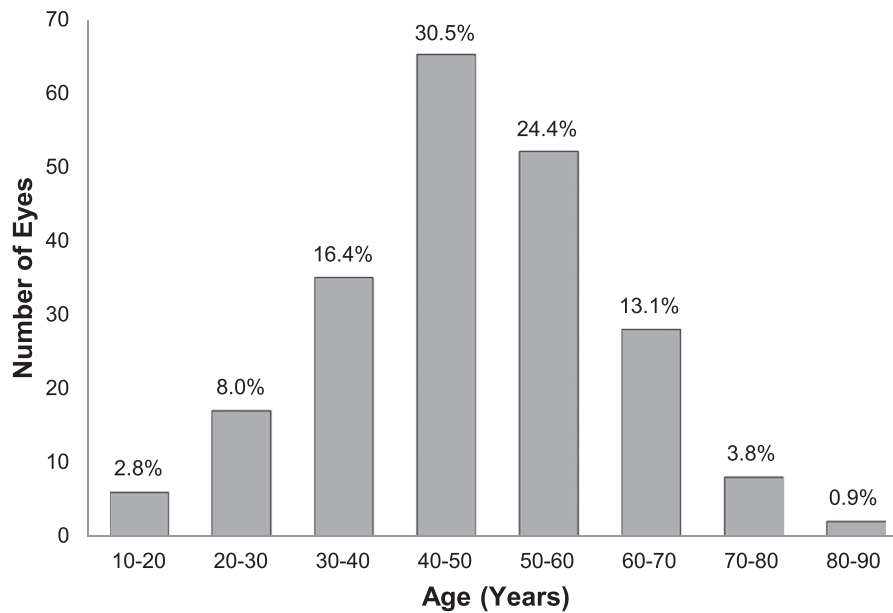


FIGURE 4.
Age distribution (N = 213 eyes).

Demography

A total of 144 patients (213 lenses) were evaluated in this study. They were composed of 80 (55.6%) males and 64 (44.4%) females. Bitangential scleral lenses were fitted bilaterally in 69 patients and unilaterally in 75 patients. The distribution of right and left eyes was almost equal: 108 right eyes and 105 left eyes. Mean age was 47.7 years (range, 11 to 86 years) (Fig. 4).

Diagnoses

In this study, we categorized the diagnoses into five main groups (Table 1). The most common diagnosis was keratoconus (121 eyes; 56.8%). In the OSD group, there were eyes with sicca problems caused by several factors (keratitis sicca, Sjögren syndrome, lagophthalmos, neurotrophic) and also eyes with recurrent corneal erosions. Irregular astigmatism included eyes with scarring related to several forms of keratitis or trauma and various corneal disorders with irregular corneal shapes, such as pellucid marginal degeneration, ectasia after refractive surgery, and Terrien marginal degeneration. The category “other diagnoses” consisted of high myopia, high astigmatism (>4 diopters), and ptosis.

Comfort

The median score for scleral lens comfort was 4. The highest scores of 4 and 5 were given for 164 lenses (77.0%). Scores of 1, 2,

and 3 were given for nine (4.2%), seven (3.3%), and 33 (15.5%) lenses, respectively.

Visual Acuity

Visual acuity outcomes are shown in Fig. 5. The decimal BCVA with the scleral lens was 0.8 (equivalent to Snellen 20/25) or better in 134 eyes (62.9%). Median decimal BCVA with the scleral lenses was 0.8 (range, 0 to 1.5). Lower BCVA outcomes occurred especially when the scleral lens had a more therapeutic than visual function, for example, as protection in patients with severe keratitis sicca and patients with scarring after herpes simplex keratitis. Poorer results were also encountered in patients with very progressive keratoconus, after keratoplasty, and in a patient with irregular astigmatism and secondary nystagmus.

Scleral Lens Characteristics

Mean overall diameter of the scleral lenses was 19.9 mm; a total of 162 lenses (76.1%) had a diameter of 20.0 mm. In 40 eyes (18.8%), smaller diameters were fitted (range, 18.5 to 19.5 mm), whereas in 11 eyes (5.2%), larger diameters were fitted (range 20.5 to 21.5 mm).

Distributions of the materials used in this study were Boston XO2 in 143 eyes (67.1%), Boston XO in 36 eyes (16.9%), Boston Equalens II in 24 eyes (11.3%), and Menicon Z in 10 eyes (4.7%).

Scleral Lens-Fitting Results

The scleral lens movement was graded as desirable (acceptable to optimal values) in 208 eyes (97.7%). Undesirable movement was encountered in five eyes (2.3%): excessive mobility in two eyes and no lens movement in three eyes (Table 2).

Almost all of the lenses showed good positioning: acceptable to central in 208 lenses (97.7%). Decentration of the scleral lens was observed most frequently in the inferior, temporal, or inferotemporal position (Fig. 6).

TABLE 1.
Diagnoses

Diagnoses (N = 213 eyes)	Eyes	Percentage
Keratoconus	121	56.8
Ocular surface diseases	31	14.6
Penetrating keratoplasty	29	13.6
Irregular astigmatism	28	13.1
Other	4	1.9
Total	213	100

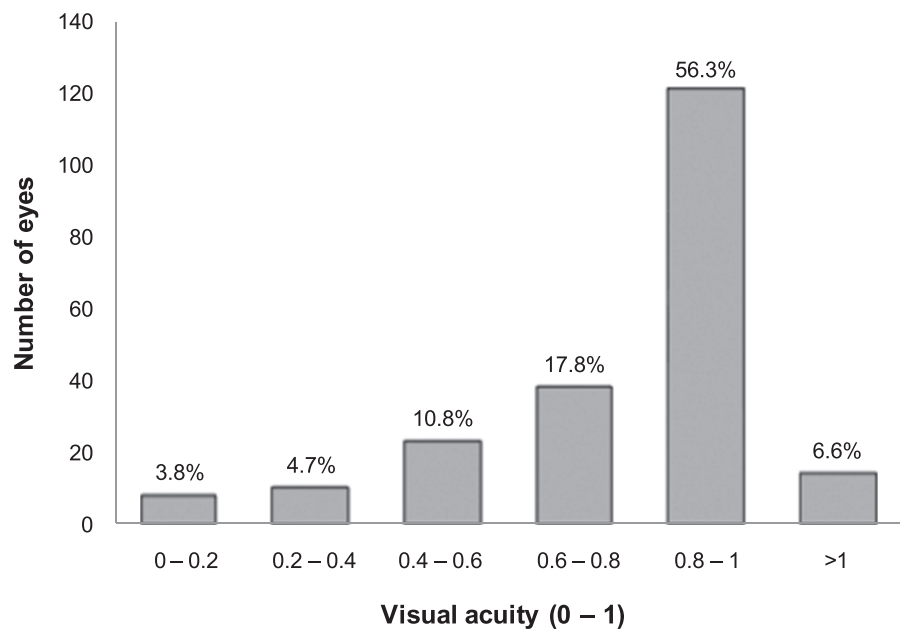


FIGURE 5.
Visual acuity (N = 213 eyes).

Median central corneal clearance was 0.2 mm (range, 0.05 to 0.6 mm). Limbal clearances differed in the four positions: the inferior and temporal values were higher than the superior and nasal values (Fig. 7). Results in the right and left eyes were fairly similar.

The stabilization axes of the flattest meridians in the right and left lenses are shown in Fig. 8. In the right eyes, the median stabilization axis was 140 degrees (range, 0 to 180 degrees); in the left eyes, it was 60 degrees (range, 0 to 180 degrees). Right lens median values fell in the area with the most stabilizations. This was not the case with the left lenses. The stabilization values had a different distribution (over two quadrants around the horizontal 0- to 180-degree axis rather than over one quadrant) (Fig. 8).

DISCUSSION

This study addressed the clinical results of the use of bitangential scleral lenses in 144 patients (213 eyes), with a variety of ocular disorders. We followed the patients in the first year after they had been fitted at our practice. Evaluations were performed on one or two lenses per subject because there was no comparison group and it was unlikely that the eyes of these patients were correlated. It was beyond the scope of this study to compare the

performance of different types of scleral lens design. Further studies on the different types are necessary to reveal differences between the lens designs.

The largest diagnostic category was keratoconus, followed by OSD, penetrating keratoplasty, and other forms of irregular astigmatism. This distribution was consistent with that in other reports on scleral contact lenses. Corneal irregularity therefore forms a leading indication for scleral lens fitting.^{6,8,9,14,19,25-28} Another well-described application for scleral lenses is OSD (mainly

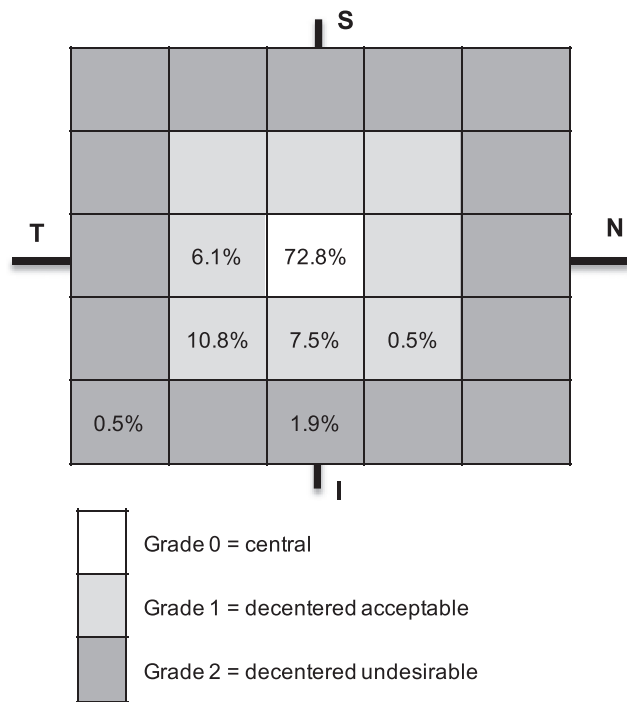


FIGURE 6.
Centration of the bitangential scleral lens (N = 213 lenses). I, inferior; N, nasal; S, superior; T, temporal.

TABLE 2.
Movement of the bitangential scleral lens

Grading	Explanation	Eyes (N = 213 eyes)	Percentage
-2	No movement	3	1.4
-1	Reduced movement acceptable	22	10.3
0	Optimal movement	162	76.1
1	Increased movement acceptable	24	11.3
2	Excessive movement unacceptable	2	0.9

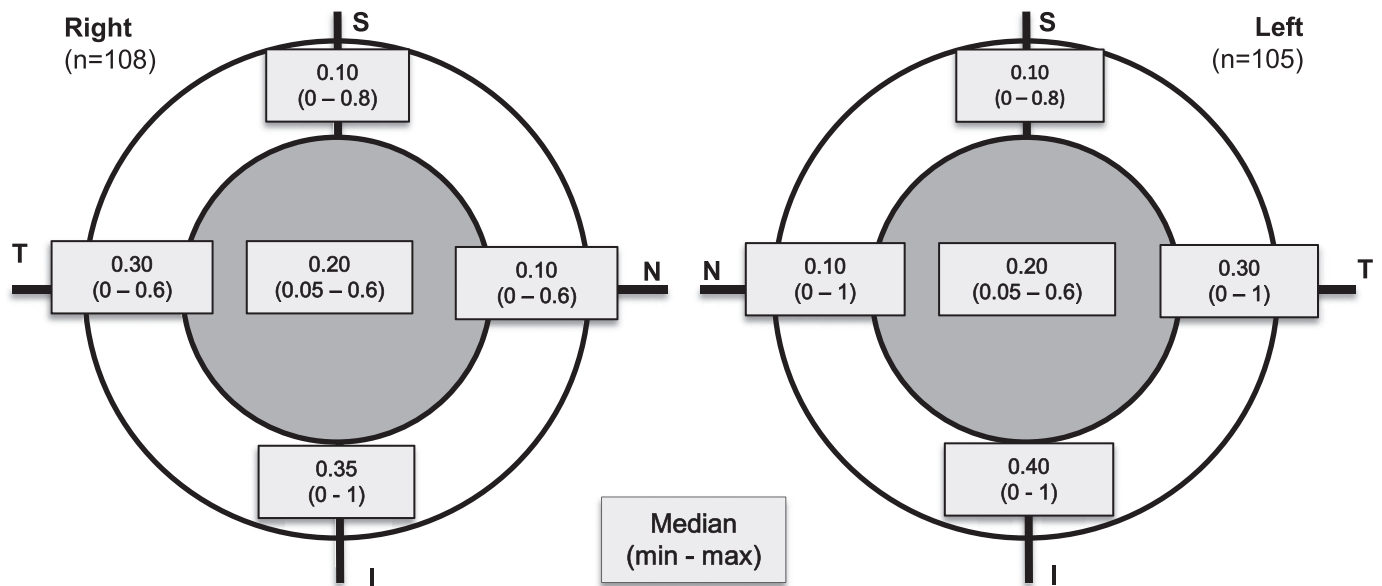


FIGURE 7.

Clearance (median [in millimeters]). I, inferior; N, nasal; S, superior; T, temporal.

keratitis sicca).^{6,28-37} Patients often experience relief or resolution of symptoms, such as dry eyes, irritation, pain, and photophobia, when wearing scleral lenses.

In our study group, age ranged from 11 to 86 years; two patients were younger than 16 years (three eyes). Gungor et al.³⁸ studied 31 patients (47 eyes) in the pediatric age group (age range, 7 months to 12.92 years), with a wide range of ocular surface and refractive disorders and observed clear benefits of scleral lenses. Rathi reviewed 20 eyes in a group of patients of 16 years or younger who had received scleral contact lenses. He concluded that these lenses were beneficial to pediatric patients but that fitting was challenging and required considerable time and patience from the parents and the clinician.³⁹ In our own experience, children are generally highly motivated and show good compliance.

Our study group also included elderly patients for whom scleral lens handling might be challenging, but scleral lenses are robust and dimensionally stable, which is advantageous for elderly and less dextrous patients.

All the scleral lenses applied in this study were fitted diagnostically with trial lenses following our standardized fitting

methodology. Schornak and Patel⁴⁰ investigated the correlation between the anterior corneal contour parameters and the base curve of scleral lenses and found only a weak predictive relationship. They concluded that, at present, the diagnostic approach seems to be the most efficient method to fit scleral lenses.⁴⁰ However, new developments in commercially available technology to measure scleral topography might become helpful in the fitting process.

Material selection was done individually. In general, the more highly oxygen-permeable materials were preferred by the scleral lens fitter. However, exceptions were made in patients who, for instance, were known to have increased protein deposits or scratched lenses. In these cases, the lower oxygen-permeable materials were advisable because they are less prone to deposits and scratching. Based on calculations, Michaud et al.⁴¹ recommended the prescription of scleral lenses with the highest Dk values available to minimize corneal hypoxia. As scleral lenses are typically thicker than corneal lenses, their relative oxygen transmissibility is lower. This applies especially to lenses with high refractive powers, which increase the central or the peripheral thickness of the

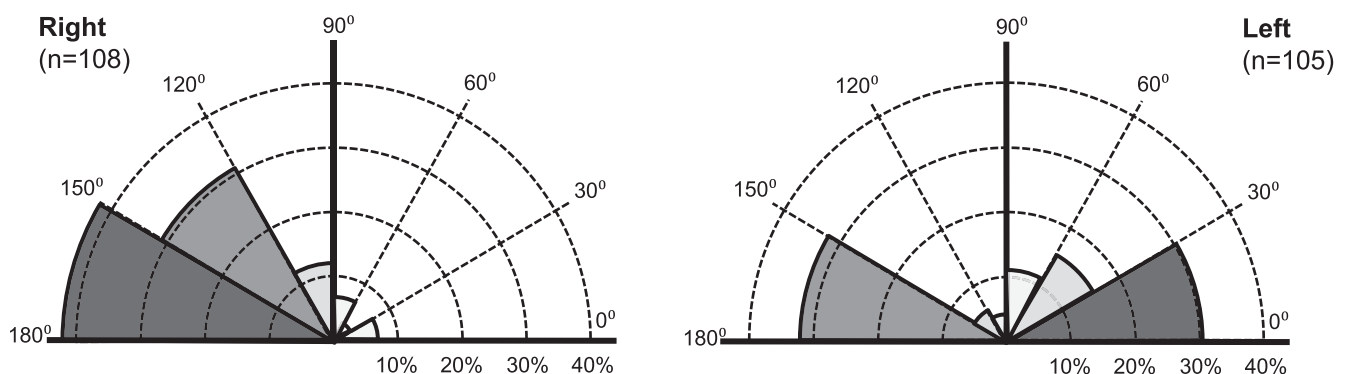


FIGURE 8.

Stabilization axes of the flattest meridians.

optical zone of the scleral lens.⁴¹ Weismann and Ye⁴² took another point into consideration, namely, that a diseased cornea may have larger or smaller oxygen requirements or possibly a larger or smaller response to hypoxia. They concluded that acceptable values of tear oxygen tension can be expected beneath the scleral lens (of 100 Fatt Dk units) under open eye conditions.⁴² The gas permeability of the Menicon Z material exceeded the recommendations made by Michaud et al.⁴¹ and should therefore provide maximum benefit for corneas that require more oxygen, for example, eyes with long-term transplants and resulting low endothelial cell counts. This hypothesis still needs to be tested. Menicon Z material did not become available until the end of our study. Therefore, it was only applied to 10 eyes.

The good performance of the scleral lenses used in our study was first expressed in the high comfort scores given by the patients: 77.0% of the lenses were rated with the highest scores of 4 or 5.

Several developments during the past few years have led to increased patient satisfaction with their scleral lenses. The introduction and use of gas-permeable materials have made scleral lenses more comfortable to wear.^{3,6,8,9,43} Previously, we reported that back surface toric scleral lenses gave greater comfort than the back surface spherical scleral lenses. Furthermore, our study on modern scleral lenses revealed high patient satisfaction with all the modern scleral lens designs (toric and spherical). Generally, scleral lenses were more comfortable than the patients' former type of correction (e.g., spectacles or other contact lenses).^{13,15}

Improvements in VA compared with spectacle correction constitute the greatest benefit of scleral lens fitting in the majority of patients. Best-corrected VA often improves enormously, as has been described in several studies.^{9,14,16,19,26–28,44} The best VA results were observed in the group with irregular corneal topography. When scleral lenses are fitted for therapeutic reasons, changes in VA are often less pronounced because, in this group of patients, the main goals are protection, tear conservation, and/or pain relief.¹⁴ In the current study, the median VA was 0.8, which was in line with previous findings.

Correct lens fitting is essential to avoid complications. In an earlier study, we found that nonoptimal lens fitting values formed a frequent reason to recommend lens refitting.¹⁴

The present study showed optimal lens fitting characteristics in the majority of eyes. Variations in clearance were in accordance with the lens position: greater clearance typically occurred in the most common directions of decentration, namely, the temporal and inferior directions.

It was remarkable that the median stabilization axis values of the lenses were very similar to those in a previous study by Visser et al.¹³ In the present study, the median in the right eyes was 140 degrees (range, 0 to 180 degrees) compared with 137 degrees (range, 30 to 180 degrees) in our earlier study; in the left eyes, it was 60 degrees (range, 0 to 180 degrees) compared with 47 degrees (range, 0 to 170 degrees) in our previous study.¹³ As the stabilization values in the left eyes were distributed over two quadrants around the horizontal 0- to 180-degree axis rather than over one quadrant, the median value did not fall within the area with the most stabilization values (Fig. 8).

In this study, the most frequently used scleral lens diameter was 20.0 mm. This was not surprising because our routine fitting

lenses have a diameter of 20.0 mm. Some patients seemed to need a larger or smaller diameter during fitting, so the most appropriate diameter was chosen. This study revealed that reductions in size (from the standard size of 20.0 mm) were more common than enlargements. Other studies also reported the application of different sizes. These lenses have been referred to as Semi-Scleral, Mini-Scleral, and Cornea-Scleral in the literature, and there is a continuum in diameter between these and scleral lenses.³⁵

The Scleral Lens Education Society has developed a classification system that defines scleral lens types on the basis of their size: Semi-Scleral (12.5 to 15.0 mm), Mini-Scleral (15.0 to 18.0 mm), and Large-Scleral (18.0 to 25.0 mm).^{22,45} Such clear categories will make it considerably easier to compare groups of patients with scleral lenses in future studies.

Renewed interest in the scleral profile and scleral lenses has resulted in new scleral lens designs, which complements and improves scleral lens practice.

This study revealed that the bitangential scleral lens fitting and performance characteristics were clear and effective for the practitioner and the patient. The tangential and nonrotationally symmetrical periphery achieved central and stable fitting of the scleral lens, which resulted in high comfort scores. The high-oxygen-permeable material Menicon Z may, in theory, be of benefit to corneas with a high oxygen demand.

The new scleral lens design with a bitangential (nonrotationally symmetrical) periphery was very beneficial to patients with OSDs and irregular corneas secondary to disease or previous surgery.

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